DEC 1 9 2012

510(k) Summary

510(k) Number:	K112644
510(K) Owner:	Lotus Bio® (NYMPHAEA) Ltd. Jabotinsky 135a Ramat Gan 52563, Israel
Submitter (US Agent):	Lori Kahler The RC Insight Group 461 Main Street, Suite 200 Pawtucket, RI 02860 Telephone: 401-722-1811 / 202-715-6242 Fax: 202-686-2877 Email: lkahler@rcinsightgroup.com
Contact:	Dr. Vered Shany, DMD, MBA CEO Telephone: +972 - 777-00-1669 Fax: +972 - 777-00-1670 Email: Vered@LotusBio.com
Manufacturer:	Lotus Bio® (NYMPHAEA) Ltd. Jabotinsky 135a Ramat-Gan 52563, Israel
Date Prepared:	17 December 2012
Trade name:	Seaforia™ Sperm Separation Assistance System
Common name:	Assisted Reproduction Labware, Assisted Reproduction Accessories
Classification name:	21 C.F.R. §884.6160 , 21 C.F.R. § 884.6120
Product Code(s):	MQK (labware, assisted reproduction), MQG (accessories, assisted reproduction)
Classification:	Class II

Legally Marketed Device - Claiming Equivalence:

RI Migration Sedimentation Chamber (MSC)
Research Instruments Ltd
K112413

MTG- Minitüb Heated Stage System
Zander Medical Supplies, Inc.
K002971

Summary Description of the Device:

The Seaforia™ Sperm Separation Assistance System separates motile/progressively motile sperm cells from debris and non-motile sperm cells from the original semen sample for further use in assisted reproductive procedures, including intrauterine insemination (IUI), intra-cervical insemination (ICI) and in-vitro fertilization (IVF). The system provides conditions such as temperature 37°C ±0.5 and effective surface area for the separation of motile human sperm cells. Note: The separation media is not included with the Seaforia™ Sperm Separation Assistance System. LOTUS BIO® requires that the media used with the Seaforia™ Sperm Separation Assistance System be a media cleared for use in the United States that is indicated for sperm handling, washing, or swim-up procedures with a formulation compatible with use outside of a CO_2 environment.

The system is composed of the following units:

- **Seaforia™ Sperm Separation Assistance System Disposable Kit** - includes designated containers (separators) for the separation media available in various volumes and labware accessories such as syringes, polypropylene tips, pipette and vials. Five versions of the kit will be available to accommodate sperm samples ranging from 0.5-6 ml (Versions 0.5-2 ml, 2.5-3.0 ml, 3.5-4.0 ml, 4.5-5.0 ml, and 5.5-6.0 ml).
- **Seaforia™ Sperm Separation Assistance System Heating Device** - capable of maintaining the sperm sample at the required temperature (37°C ±0.5).

The sperm separation procedure takes place within the separator and is based on the original swim-up technique. Media is layered over the liquefied semen sample and during a subsequent incubation period of 30 minutes in the Seaforia™ Sperm Separation Assistance System Heating Device, the motile sperm cells migrate from the semen layer into the media.

Indications for Use/Intended Use:

The Seaforia™ Sperm Separation Assistance System consists of the following components:

The Seaforia™ Sperm Separation Assistance System Disposable Kit (Versions 0.5-2 ml, 2.5-3.0 ml, 3.5-4.0 ml, 4.5-5.0 ml, and 5.5-6.0 ml)

The Seaforia ™ Sperm Separation Assistance System Disposable Kit is intended for preparing motile sperm using the swim-up (SU) separation method and holding sperm for use in assisted reproductive procedures such as intrauterine insemination (IUI), intra-cervical insemination (ICI) and in-vitro fertilization (IVF). The Seaforia™ Sperm Separation Assistance System Disposable Kit is indicated for incubation periods not exceeding one (1) hour.

The Seaforia™ Sperm Separation Assistance System Heating Device

The Seaforia ™ Sperm Separation Assistance System Heating Device is indicated for use only with the Seaforia ™ Sperm Separation Assistance System Disposable Kit to maintain the temperature (37°C ±0.5) of sperm during the swim-up (SU) separation procedure.

Substantial Equivalence Summary:

The Seaforia™ Sperm Separation Assistance System is substantially equivalent to the Research Instruments Ltd Migration Sedimentation Chamber (K112413) and to the MTG-Minitüb Heated Stage System (K002971).

The Seaforia™ Sperm Separation Assistance System Disposable Kit and the Research Instruments Ltd Migration Sedimentation Chamber (K112413) have equivalent intended use and indications for use as assisted reproduction labware to aid in the separation of motile sperm from liquefied semen for use in assisted reproductive medicine applications. The Seaforia™ Sperm Separation Assistance System Disposable Kit and the RI Migration Sedimentation Chamber (MSC) are both disposable devices and are made of materials commonly used in assisted reproduction labware. All components of the Seaforia™ Sperm Separation Assistance System Disposable Kit are made of polypropylene except for the pipettes which are made from a low density polyethylene, while the RI MSC is made from polystyrene. The main difference between the Seaforia™ Sperm Separation Assistance System Disposable Kit and the RI MSC is that the disposable kit contains designated containers for different semen volume and accessories (such as syringes, polypropylene tips, pipette, and vials) whereas the RI MSC device is a single device rather than a kit. Both the Seaforia™ Sperm Separation Assistance System Disposable Kit and the RI MSC are indicated for use in preparing sperm in assisted reproduction procedures. Both the Seaforia™ Sperm Separation Assistance System Disposable Kit and the RI MSC use a comparable swim-up procedure and collection principal. The only minor difference in the design between the predicate device and the proposed device is the Seaforia™ System method of loading and collecting that requires the use of designated containers and accessories to aid in sperm separation procedure (such as syringes, polypropylene tips, pipette, and vials). The differences in the design do not impact the swim-up procedure and collection method. Regarding the Seaforia™ Sperm Separation Assistance System Disposable Kit HSSA specification: as the Seaforia™ Sperm Separation Assistance System Disposable Kit is

indicated for incubation periods of 30 minutes (should not exceed one (1) hour); the HSSA assessment was completed at 1 hour. The predicate's assessment was completed at 24 hours; however, the predicate device is also indicated for sample storage and the sperm is pre-loaded with culture media two hours prior to the moment of insemination. The proposed device has a short incubation period and is not indicated for sample storage. The HSSA assessment completed at 1 hour is appropriate for the use of the proposed device.
In addition, the Seaforia™ Sperm Separation Assistance System is also for use in assisted reproductive procedures such as intra-cervical insemination (ICI) whereas the RI MSC is not indicated for use with ICI. This difference would not represent a new intended use as intra-cervical insemination (ICI) is a common method of assisted reproduction.

The Seaforia™ Sperm Separation Assistance System Heating Device and the MTG-Minitüb Heated Stage System (K002971) are equivalent with respect to intended use, indications for use and technological characteristics as a heating device used to warm biological material. The MTG-Minitüb Heated Stage System (K002971) has a wider variation of temperature range (ambient temperature through 55°C with a control accuracy +/- 0.2°C) while the Seaforia™ Heating Device maintains a temperature of 37°C ±0.5. The differences do not affect the safety and effectiveness of the device and does not impact the use of the identified predicate to support an equivalence decision.

The following detailed substantial equivalence table compares the Seaforia™ Sperm Separation Assistance System with the predicate devices.

Substantial Equivalence Table

	New Device	Predicate Device	Predicate Device
510(k) #		K002971	K112413
Company	Lotus Bio® (NYMPHAEA) Ltd.	Zander Medical Supplies, Inc.	Research Instruments Ltd.
Name	Seaforia™	MTG-Minitüb Heated Stage System	RI MSC
Classification/ Regulation	Class II / 884.6160, 884.6120	Class II / 884.6120	Class II / 884.6160
Product Code	Disposable Kit: MQK (labware, assisted reproduction Heating Device: MQG (accessories, assisted reproduction);)	MQG (accessories, assisted reproduction)	MQK (labware, assisted reproduction)
Indications for Use – Disposable Kit	The Seaforia™ Sperm Separation Assistance System Disposable Kit The Seaforia ™ Sperm Separation Assistance System Disposable Kit is intended for preparing motile sperm using the swim-up (SU) separation method and holding sperm for use in assisted reproductive procedures such as intrauterine insemination (IUI), intra-cervical insemination (ICI) and in-vitro fertilization	n/a	The RI MSC is intended to prepare sperm by migration-sedimentation method for the assisted reproduction techniques of intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI).

	New Device	Predicate Device	Predicate Device
	(IVF). The Seaforia™ Sperm Separation Assistance System Disposable Kit is indicated for incubation periods not exceeding one (1) hour.		
Indications for Use – Heating Device	The Seaforia™ Sperm Separation Assistance System Heating Device The Seaforia ™ Sperm Separation Assistance System Heating Device is indicated for use only with the Seaforia ™ Sperm Separation Assistance System Disposable Kit to maintain the temperature (37°C ±0.5) of sperm during the swim-up (SU) separation procedure.	Maintaining the temperature of biological material like gametes and embryos at a certain temperature is essential to cover multiple applications in reproductive medicine, biology and other areas.	n/a
Disposable Materials	Polypropylene; low density polyethylene (pipette only)	n/a	Medical grade polystyrene – non treated
Design Features – Disposable Kit	The Disposable Kit contains designated containers (for different semen volume) and accessories (such as syringes, polypropylene tips, pipette, and vials). The kits are suitable for variable semen volume 0.5-6ml. The containers are made of polypropylene.	n/a	Cylindrical container with internal gallery and well. Optically clear, with flat base.
Design Features – Heating Device	Switch on/off toggle: PC+ABS GE C2950 plastic protective case. Temperature range 37°C ±0.5. Output 5.0 VDC ± 5%, 1000mA	Control Units: metal casing protects electronic control unit – Digital displays and touch pads control and monitor the temperature. Temperature range: ambient temperature through 55°C. Control accuracy +/- 0.2°C. All control units can be switched between 200-240V/50Hz or 100-120V/60Hz.	n/a
Sterile	Disposable Kit: Yes, Sterile (SAL 10^{-6}), via gamma irradiation Heating Device: n/a	n/a	Yes, Sterile (SAL 10^{-6}), via gamma irradiation
HSSA	HSSA ≥ 70% motility following 1 hour	n/a	HSSA ≥ 70% motility at 24hr
Cytotoxicity	Cytotoxicity tested per ISO 10993-5:2009.	n/a	*Not known*
Endotoxin (LAL)	Disposable Kit: Tested non-pyrogenic by LAL Acceptance Criteria: <20.0 EU/ Device Heating Device: n/a	n/a	Tested non-pyrogenic by LAL: <0.5 EU/Device

	New Device	Predicate Device	Predicate Device
Contraindications	Not recommended for original semen samples containing less than 30% progressive motility.	n/a	Not recommended for sperm samples with total motility rate < 40%.

Technical Characteristics:

The Seaforia™ Sperm Separation Assistance System Disposable Kit

The Seaforia™ Sperm Separation Assistance System Disposable Kit contains 4 designated separator containers (for different semen volume) and accessories (three syringes, 3 polypropylene tips, 1 pipette, and 1 vial). The kits are suitable for variable semen volume 0.5-6ml. The separator containers are made of polypropylene.

The Seaforia™ Sperm Separation Assistance System Disposable Kit (separators and accessories) are sterilized by gamma irradiation to achieve SAL of 10^{-6}. The kit components are non-pyrogenic as tested by the limulus amebocyte lysate (LAL) assay, non-cytotoxic as tested by the cytotoxicity assay, and non-sperm toxic as tested by the human sperm survival assay (HSSA). Endotoxin testing/LAL (<20 EU/device) and HSSA testing (≥ 70% motility following 1 hour of exposure) are conducted as lot specific testing parameters per release activities.

The Seaforia™ Sperm Separation Assistance System Heating Device

The Seaforia™ Sperm Separation Assistance System Heating Device is a warming unit with a pre-set temperature of 37°C±0.5. The Heating Device structure is designed to fit 3 separators at the same time. The Heating Unit is powered by 5V 1000mA and is intended for multiple use.

Electromagnetic Compatibility/Electrical Safety:

Medical electrical equipment testing has been completed in accordance to IEC 60601-1, Medical Electrical Equipment – Part 1 General Requirements for Safety, 1988; Amendment 1, 1991, Amendment 2, 1995. Electromagnetic Compatibility (EMC) testing was conducted in accordance with applicable parts of AAMI/ANSI/IEC 60601-1-2, Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (Editions 2:2001 with Amendment 1: 2004).

Performance Testing - Bench:

Performance testing on the Seaforia™ Sperm Separation Assistance System was completed to assure that the device performed as intended in accordance with design and functional specifications. The following performance testing was conducted:

1. Efficacy testing of sperm preparation using the Seaforia™ Sperm Separation Assistance System

   The test was designed to confirm that by using the Seaforia™ Sperm Separation Assistance System, the separation process yields an end product with improved characteristics relative to the original semen sample. Results showed that media overlaying semen in the separators was enriched with motile sperm cells characterized by progressive motility and improved percentage of normal morphology, leaving most round non-sperm cells and immotile sperm cells behind. Therefore, testing confirmed that separation using the Seaforia™ Sperm Separation Assistance System resulted in an end product with improved characteristics as compared to the original semen sample.

2. Thermal verification test for the Seaforia™ Sperm Separation Assistance System Heating Device

   Thermal verification testing was conducted to validate the thermal performance of the Seaforia Sperm Separation Assistance System Heating Device. Testing showed that devices met the acceptance criteria (temperature maintenance at 37 ± 0.5°C).

Summary of Sterilization and Shelf Life:

The Seaforia™ Sperm Separation Assistance System Disposable Kit is sterilized by gamma-irradiation overkill VDmax method at 25 KGy. The heating device has also undergone validation testing to support the cleaning and disinfection procedures included in device labeling.

The Seaforia™ Sperm Separation Assistance System Disposable Kit has a shelf-life of 1 year from the date of manufacture and should be stored at room temperature.

Conclusion:

The Seaforia™ Sperm Separation Assistance System Disposable Kit and the Research Instruments Ltd Migration Sedimentation Chamber (K112413) have equivalent intended use, indications for use and technological characteristics for use in preparing sperm for use in assisted reproductive procedures. The Seaforia™ Sperm Separation Assistance System Heating Device and the MTG-Minitüb Heated Stage System (K002971) are equivalent with respect to intended use, indications for use and technological characteristics as a heating device for use in assisted reproductive procedures.

The Seaforia™ Sperm Separation Assistance System is substantially equivalent to the predicate devices which have equivalent intended use, indications for use and technological characteristics. There are no differences between the Seaforia™ Sperm Separation Assistance System and the predicate devices that would raise new types of

safety or effectiveness issues. The Seaforia™ Sperm Separation Assistance System is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2012

Lotus Bio® (NYMPHAEA) Ltd.
% Ms. Lori Kahler
President
The RC Insight Group
461 Main Street, Suite 217
PAWTUCKET RI 02860

Re: K112644
Trade/Device Name: Seaforia™ Sperm Seperation Assistance System
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK, MQG
Dated: November 10, 2012
Received: November 27, 2012

Dear Ms. Kahler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.0 Indications for Use

510(k) Number (if known): K112644

Device Name: Seaforia™ Sperm Separation Assistance System

Indications for Use:

The Seaforia™ Sperm Separation Assistance System consists of the following components:

The Seaforia™ Sperm Separation Assistance System Disposable Kit (Versions 0.5-2 ml, 2.5-3.0 ml, 3.5-4.0 ml, 4.5-5.0 ml, and 5.5-6.0 ml)

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The Seaforia™ Sperm Separation Assistance System Heating Device

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2012.12.19 15:10:46 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112644